RUSS, AUGUST & KABAT
Marc A. Fenster, State Bar No. 181067
Email: mfenster@raklaw.com
Bruce D. Kuyper, State Bar No. 144969
Email: bkuyper@raklaw.com
Alexander C.D. Giza, State Bar No. 212327
Email: agiza@raklaw.com
Andrew D. Weiss, State Bar No. 232974
Email: aweiss@raklaw.com
12424 Wilshire Boulevard, 12th Floor
Los Angeles, California 90025
Telephone: (310) 826-7474
Facsimile: (310) 826-6991

Attorneys for Plaintiff
NEUROGRAFIX

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA – WESTERN DIVISION

NEUROGRAFIX, a California corporation; WASHINGTON RESEARCH FOUNDATION, a not-for-profit Washington corporation,

Plaintiffs,

vs.

SIEMENS MEDICAL SOLUTIONS USA, INC., a Delaware corporation; and SIEMENS AKTIENGESELLSCHAFT, a German Corporation,

Defendants.

Case No. 10-CV-1990 MRP (RZx)

[Assigned to The Honorable Mariana R. Pfaelzer]

REBUTTAL EXPERT REPORT OF DR. AARON FILLER, M.D., PH.D, FRCS TO THE EXPERT REPORT OF MICHAEL E. MOSELEY CONCERNING U.S. PATENT NO. 5,560,360

First Amended Complaint Filed: July 30, 2010

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I. SUMMARY OF OPINIONS.

1. This report sets forth my responses to the opinions set forth by Michael E. Moseley in his expert report, dated January 24, 2011.

2. My opinion describes how a person having ordinary skill in the art would have understood the terms "conspicuity of the nerve that is at least 1.1 times that of [the]/[any adjacent] non-neural tissue" and "the nerve at an intensity at least 5 times that of the non-neural tissue." In particular, this report expresses my disagreement with Dr. Moseley that a person having ordinary skill in the art would not have been able to discern the boundaries of these terms.

3. First, based on the specification and the file history, one of skill in the art would have understood that "conspicuity" means "contrast (in, for example, intensity and color)." Indeed, the specification expressly defines "conspicuity" as such.

4. A person having ordinary skill in the art at the time of the application would know that the conspicuity of 1.1 phrases, as used in the context of the patent, mean that the ratio of the signal intensity from the nerve to the signal intensity of [the]/[any adjacent] non-neural tissue must be greater than 1.1. Said another way, the signal intensity of the nerve must be more than 10% greater than the signal intensity of the adjacent non-neural tissue. So one of skill in the art would know that conspicuity is determined by taking a ratio of the signal intensity from the nerve to the signal intensity from the non-neural tissue. Dr. Moseley seems to acknowledge that one of skill in the art would understand that conspicuity is determined by taking a ratio of signal intensities.

5. I disagree strongly with Dr. Moseley's conclusion that one of skill would not know how to determine conspicuity. Specifically, I disagree with

Dr. Moseley's suggestion that one of skill would not know what signal intensities to use in determining the ratio of signal intensities.

6. As described below, the specification describes using the average signal intensity from the nerve region of interest. Not only is this consistent with the methods accepted and described in the contemporaneous literature, but it is exactly the method that Dr. Moseley himself describes using in two different papers that predate the date of the application. Accordingly, Dr. Moseley's own publications show that he knew how to determine conspicuity as of the application date, and that he viewed it exactly as it is described in the specification, and as proposed by NeuroGrafix.

7. The contemporaneous literature discloses a commonly accepted method for calculating conspicuity. This method, which is supported by Dr. Moseley's own papers, is to take the ratio of the signal intensity of the nerve to the signal intensity of the non-neural tissue. This is also the method that one having ordinary skill in that art would have understood to have been disclosed by the '360 patent. A ratio of at least 1.1 shows at least a 10% difference.

8. In the vast majority of cases (in fact in all the cases of which I am aware, which number over ten thousand), the precise method of measuring conspicuity does not change whether a data set generated by the method claimed in the '360 patent has a conspicuity of at least 1.1 times – in almost all cases, the conspicuity is significantly higher.

9. I base my opinion on the materials considered by Dr. Moseley, including the '360 patent, its prosecution history and provisional applications included in the file history, NeuroGrafix's infringement contentions, the parties respective claim construction disclosures and the materials cited below. A complete list of the material I considered is listed in Exhibit B. I

also base my opinions on my comprehensive education, research, knowledge and experience of over 15 years.

II. INTRODUCTION.

10. I have been asked to review Dr. Moseley's expert report and provide my opinions in response to his report. I disagree with Dr. Moseley's opinion that one having ordinary skill in the art would not be able to discern the boundaries of any claims that contain the terms "conspicuity of the nerve that is at least 1.1 times that of [the]/[any adjacent] non-neural tissue" and "the nerve at an intensity at least 5 times that of the non-neural tissue."

11. It is my understanding that Defendants have asserted that both claim terms are indefinite.

12. It is my understanding that NeuroGrafix has proposed the following constructions for each term:

Terms	Construction
conspicuity of the nerve that is at least 1.1 times that of the non-neural tissue conspicuity of the nerve that is at least 1.1 times that of any adjacent non-neural tissue	contrast (in, for example, intensity and color) between the nerve and [the]/[any adjacent] non-neural tissue is at least 1.1 times
the nerve at an intensity at least 5 times that of the non-neural tissue	contrast (in, for example, intensity and color) between the nerve and any adjacent non-neural tissue is at least 1.1 times

13. It is my understanding that the parties agree that intensity in the second term is coextensive with conspicuity.

III. QUALIFICATIONS.

14. I incorporate by reference the qualifications in my opening expert report, including my CV, served January 24, 2011.

IV. PERSON HAVING ORDINARY SKILL IN THE ART.

15. As in my opening report, I am informed that, at this time, NeuroGrafix believes that a person having ordinary skill in the art for the '360 patent is a medical doctor with an M.D., three years of residency and a 1 year fellowship in neuroradiology or musculoskeletal radiology and at least 2 years experience in neuroradiology or musculoskeletal radiology, or equivalent education and experience in neuroradiology or musculoskeletal radiology. A person having ordinary skill in the art will also have substantial experience (*e.g.*, 2 years) designing or studying MRI machines.

16. I disagree with Dr. Moseley's opinion that one having ordinary skill in the art need not be a medical doctor. The invention in the '360 patent is a novel imaging technique to allow medical doctors to successfully and consistently image peripheral nerves. Thus, a person having ordinary skill in the art must at least have a medical degree and the requisite experience. This requirement also ensures that the images are prepared by a person with a special duty of care for the patient being imaged.

V. UNDERSTANDING OF THE LAW.

17. I incorporate by reference my understanding of the law from my opening expert report, served January 24, 2011.

18. It is further my understanding that a claim term is deemed indefinite if one skill in the art would understand the bounds of the claim when read in the light of the intrinsic evidence. If the meaning of a term is discernable, the term will be considered definite even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree.

VI. MEANING OF THE DISPUTED TERMS TO ONE HAVING ORDINARY SKILL IN THE ART.

19. It is my understanding that the parties have agreed that, in the context of the claims, the terms "conspicuity" and "intensity" will have similar

meanings. This understanding is also demonstrated by Dr. Moseley treating the terms as synonyms in his report.

20. Based on the patent specification and the file history, one having ordinary skill in the art would understand the term "conspicuity of the nerve that is at least 1.1 times that of [the]/[any adjacent] non-neural tissue" to mean "contrast (in, for example, intensity or color) between the nerve and [the]/[any adjacent] non-neural tissue is at least 1.1 times."

21. The specification expressly defines conspicuity: "These neurograms exhibit a high nerve conspicuity, which for the purpose of the ensuing discussion will be understood to refer to the contrast (in, for example, intensity or color) between the nerve and the image background." '360 patent at 11:56-59. Thus, the patent defines "conspicuity" as "the contrast (in, for example, intensity or color)."

22. This definition is consistent with the statements made in the file history: "The nerve 'conspicuity' refers to the contrast (in, for example, the intensity or color) between the nerve, and the image background." '360 patent file history at November 14, 1994 Amendment And Request For Reconsideration at 11.

23. Thus, one having ordinary skill in the art would understand that "conspicuity of the nerve that is at least 1.1 times that of [the]/[any adjacent] non-neural tissue" means "the contrast (in, for example, intensity or color) between the nerve and [the]/[any adjacent] non-neural tissue is at least 1.1 times."

24. For the same reasons, because claim 19 is dependent on claim 18, one having ordinary skill in the art would understand that "the nerve at an intensity at least 5 times that of the non-neural tissue" means "the contrast

(in, for example, intensity or color) between the nerve and any adjacent non-neural tissue is at least 5 times."

VII. ONE HAVING ORDINARY SKILL IN THE ART THE TIME OF THE APPLICATION WOULD UNDERSTAND HOW TO QUANTIFY CONSPICUITY.

25. A person having ordinary skill in the art at the time of the application would know that the conspicuity of 1.1 phrases, as used in the context of the patent, means that the ratio of the signal intensity from the nerve to the signal intensity of [the]/[any adjacent] non-neural tissue must be greater than 1.1. In other words, the signal intensity of the nerve must be more than 10% greater than the signal intensity of the adjacent non-neural tissue (because 1.1 is 10% greater than one). Thus, a person having ordinary skill in the art knows that the term refers to the signal intensity of the nerve being at least 10% greater than the signal intensity of [the]/[any adjacent] non-neural tissue.

26. Dr. Moseley seems to acknowledge that one of skill in the art would understand that conspicuity is determined by taking a ratio of signal intensities, as each of his proposed methods of calculating conspicuity (most of which are not valid, as described below), are all variations based on taking a ratio of a signal intensity from the nerve to a signal intensity from the surrounding tissue. See, e.g., Moseley ¶¶ 24-27.[1]

27. In the context of the intrinsic evidence, one having ordinary skill in the art would know how to determine if the signal intensity of the nerve is at least 10% greater than the signal of the [the]/[any adjacent] non-neural tissue.

[1] As described below, Dr. Moseley's citation to Hallberg and Seeley in ¶¶ 30 and 31 of his report is misplaced, as those papers did not relate to MRI. *See* ¶¶ 44-45, below.

A. The Patent Describes A Method For Calculating Conspicuity.

28. How to determine whether the signal intensity of the nerve is at least 10% greater than the signal intensity of the adjacent non-neural tissue is clear to those of skill in the art, particularly in light of the specification. As Dr. Moseley appears to recognize by quoting the specification and the various equations that he asserts can be used to calculate conspicuity, one having ordinary skill in the art understands that conspicuity in the context of the '360 patent is the ratio of the signal intensities of the nerve to the signal intensities of the non-neural tissue. If that ratio is greater than 1.1 (or 5 for claim 19), it meets the claim.

29. As explained below, the patent expressly defines conspicuity as contrast, which one of skill understands means a ratio of the signal intensity of the region of interest to the signal intensity of the non-neural tissue.

30. When read by a person having ordinary skill in the art, the claims and specification also disclose an exemplary method for calculating conspicuity. As discussed above, the specification discloses that the average intensity within a region of interest (which can be a voxel or larger region) is calculated at block 124 of Figure 10. '360 patent at 14:63-15:11 (the intensity can be represented by the following equation: "$S=A_o$ [exp (-TE/T_2)][exp (-bD)]"). The specification includes a description of calculating the average intensity for the region of interest. '360 patent at 14:63-64 ("the average image or pixel intensity within each ROI is computed"). The specification also discloses using the average intensity within a region of interest in other portions of the specification. *See, e.g.*, '360 patent at 28:2-7 ("First, a thresholding process is used to identify relatively bright regions of the image potentially representative of nerve. With the boundaries of these

regions established, the intensity of the pixels associated with each region is evaluated and average image intensities for the regions are computed."

31. A person having ordinary skill in the art at the time of the application knew that the average intensity for a region of interest is used for, among other things, measuring conspicuity by taking the ratio of the average intensity for the region of interest to the average intensity of the non-neural tissue. This is further supported by the claims that disclose that the conspicuity of the nerve must be 1.1 times greater than surrounding non-neural tissue. *See, e.g.*, '360 patent at claims 1, 18, 19; 23:56-63; 6:39-45.

32. Thus, the specification describes the following method for calculating conspicuity: dividing the average signal intensity from the nerve by the average intensity of the surrounding non-neural tissue. *See, e.g.*, '360 patent at 14:63-15:11; 23:56-63; 6:39-45; claims 1, 18, 19. Some of the claims provide additional limitations regarding the specific non-neural tissue to choose (*e.g.*, adjacent non-neural tissue in claim 18)

33. Thus, it is my opinion that, despite the statement in paragraph 9 of Dr. Moseley's report, the patent does in fact disclose the method used to calculate conspicuity.

B. The Intrinsic Evidence Is Consistent With The Literature That Discloses The Ratio Method To Calculate Conspicuity.

34. The intrinsic evidence is consistent with the contemporaneous literature regarding the calculation of conspicuity. As one notable example, the ratio method described above was disclosed and used by Dr. Moseley in his contemporaneous papers. *See, e.g.*, M.E. Moseley et al., *Diffusion-Weighted MR Imaging of Acute Stroke: Correlation with T2-Weighted and Magnetic Susceptibility-Enhanced MR Imaging in Cats,* ANJR 11:423-29 (May/June 1990); M.E. Moseley et al., *Comparison of Gd- and Dy-Chelates*

for T2 Contrast-Enhanced Imaging**, Magnetic Resonance In Medicine 22, 259-64 (1991) (referring to ANJR 1990 paper for explanation how to calculate conspicuity); M.E. Moseley et al., *Early Detection of Regional Cerebral Ischemia in Cats: Comparison of Diffusion- and T2-Weighted MRI and Spectroscopy*, Magnetic Resonance in Medicine 14:330-346 (1990).

35. For the reasons state above, it is my opinion that one skilled in the art would know exactly how to calculate the required conspicuity given the information in the '360 specification and claims when considered in the light of the literature available at that time.

VIII. MY OPINIONS REGARDING THE MOSELEY REPORT.

36. I have carefully reviewed Dr. Moseley's report and the evidence he relied on. I disagree with many of his opinions.

A. Dr. Moseley's Statements Regarding Calculating Conspicuity Fail To Account For The Knowledge Of One Skill In The Art At The Time Of The Application.

37. I disagree with Dr. Moseley's statements, in for example paragraphs 9 and 21, that the claims, specification and file history of the '360 patent do not provide a way of quantifying conspicuity. In fact, as I discuss above, when read by a person having ordinary skill in the art, the claims and specification do disclose how to calculate conspicuity. Moreover, the method disclosed is supported by Dr. Moseley's own contemporaneous articles disclosing how one of skill in the art calculated conspicuity at the time of the application. The algorithm disclosed in the patent and in Dr. Moseley's writings is the algorithm cited by Dr. Moseley in paragraph 25 of his report. Once one acknowledges, as Dr. Moseley does, that conspicuity is determined by taking the ratio of signal intensities for nerve and adjacent non-neural tissue, one of skill would know how to make that determination. Dr. Moseley incorrectly asserts that there are several such possibilities,

which he describes in ¶¶ 24 to 27 of his report. In Paragraph 25, he describes the method described in the patent specification and that described in the contemporaneous literature (including Dr. Moseley's own papers): the average intensity of the nerve divided by the average intensity of the adjacent non-neural tissue.

38. Dr. Moseley is mistaken when he opines in paragraph 25 that average may be mean, median, or mode. A person having ordinary skill in the art at the time would have known average meant mean. This is further supported by the equation disclosed at column 14, line 67 of the '360 patent and contemporaneous evidence. *See* E.J. Borokowski et al., The HarperCollins Dictionary of Mathematics at 39, 369, 371, 373, 383 (defining "mean" as another word for average; providing separate definitions for median and mode). Further, it is explicitly stated that the "mean" should be used for this purpose in M.E. Moseley et al., Early Detection of Regional Cerebral Ischemia in Cats: Comparison of Diffusion- and T2-Weighted MRI and Spectroscopy, Magnetic Resonance in Medicine 14:330-346 at 332 (1990).

39. The other possible methods, described in ¶¶ 24, 26 and 27, are not supported in the literature. Dr. Moseley provides no basis to support his assertion that anyone of skill in the art would think to calculate conspicuity by these methods.

40. In my opinion, Dr. Moseley is wrong to opine that a person having ordinary skill in the art would think that that conspicuity could be calculated by comparing only the maximum or minimum voxels of the nerve and non-neural tissue. See Moseley Report, ¶¶ 26, 27. With respect to the comparison of the maximum intensity of a nerve to the maximum intensity of the non-neural tissue, this is not a reasonable calculation from a medical or biological point of view because a single errant very bright pixel in the

non-neural tissue would result in small conspicuity despite the fact that the nerve is clearly more conspicuous than the non-neural tissue.

41. For the comparison of minimum intensities, it also ignores important, basic medical and technical information within the knowledge of one having ordinary skill in the art. Depending on resolution, intra-nerve signal intensity can be very low and non-neural tissue can have an effective signal intensity of zero, which would cause a division by zero calculation error. Although it is true that the zero division problem could be solved by substituting 1 for zero, it is further the case that using such an algorithm would lead to a situation where if a nerve that is bright has a single pixel inside it that it rendered dark because of rapid blood flow in a small artery at the center of the nerve, then the entire nerve would be treated as dark even though it was obviously bright. These non-sensical results are inimical to patient care.

42. Dr. Moseley also fails to cite to any literature that supports using either the maximum or minimum proposed methods to calculate conspicuity in an MRI data set. As discussed above, Dr. Moseley's own papers use the method disclosed in the patent.

43. In my opinion, Dr. Moseley is also wrong in paragraphs 29-31 where he opines that one having ordinary skill in the art would understand conspicuity to mean more than the definition expressly included in the specification and file history. As discussed above, the contemporaneous literature at the time is consistent with the definition in the intrinsic evidence. *See, e.g.*, M.E. Moseley et al., *Diffusion-Weighted MR Imaging of Acute Stroke: Correlation with T2-Weighted and Magnetic Susceptibility-Enhanced MR Imaging in Cats,* ANJR 11:423-29 (May/June 1990); M.E. Moseley et al., *Comparison of Gd- and Dy-Chelates for T2* Contrast-*

*Enhanced Imaging**, Magnetic Resonance In Medicine 22, 259-64 (1991) (referring to ANJR 1990 paper for explanation how to calculate conspicuity); M.E. Moseley et al., *Early Detection of Regional Cerebral Ischemia in Cats: Comparison of Diffusion- and T2-Weighted MRI and Spectroscopy*, Magnetic Resonance in Medicine 14:330-346 (1990).

44. Furthermore, Dr. Moseley's citation to the conspicuity algorithms disclosed in Hallberg et al. and Seeley et al. is inappropriate and misleading. Both Hallberg et al. and Seeley et al. address calculating conspicuity in an X-ray, not an MRI. In an X-ray, the entire volume appears as a flattened projection on a single image plane so that, for example, a rib passing a few inches behind the lung and a lesion will be seen through both of them. Thus, as a result of this flattening, conspicuity must be calculated by taking data points from both the lesion (which includes data other than the lesion) and the surrounding field image. An MRI image, however, does not suffer from the same flattened projection image issues. If the techniques taught by Hallberg et al. and Seeley et al. were to be used for an MRI cross section of nerve, then complexity occurring only within the nerve would be added to the area around it. A person having ordinary skill in the art would understand the inappropriateness of this. As a result, the methods described in both Hallberg et al. and Seeley et al. are not appropriate for an MRI and one having ordinary skill in the art would know that the cited algorithms are irrelevant.

45. I have also been unable to find any papers, either in the 1992 time frame or later, where either the Hallberg et al. or the Seeley et al. method is used to calculate conspicuity in an MRI data set.

46. In paragraphs 22-32, Dr. Moseley discussed and shows that the algorithms he cites will result in different data. This statement is irrelevant

for two reasons. First, as discussed above, the algorithms he cites are not supported in the literature and would not be used by one of skill in the art for MRI (except for the one described in the specification and in ¶25 of his report). Second, while the different MRI-related algorithms referenced by Dr. Moseley (paragraphs 24-27) will produce slightly different data, the differences are insignificant in determining whether an image meets the threshold of being 1.1 times.

47. Dr. Moseley's own Table 1 on page 11 of his report proves this point. Although Dr. Moseley does not use an image of a peripheral nerve[2] and does not indicate the pulse sequence used to generate the image used to generate Table 1 (and it does not appear to be consistent with various claims as it appears to fail to include fat suppression), it is clear that all of the calculations do not differ very much.[3] They all show, unsurprising, that the image (if made using the disclosed method) did not infringe.

48. The tables in Exhibit A related to Figures 2, 3 and 4[4] illustrate similar calculations to Dr. Moseley's Table 1. The images used, however, were made using the method disclosed by the claims. As can be seen, regardless of the method used (mean, min, max, max-min) and non-neural tissue chosen, the results are the same: the nerve has a conspicuity of 1.1 times more than the non-neural tissue. Additionally, in my experience of reading

[2] Dr. Moseley is using an image of the neck and the region of interest is the spinal cord, a part of the central nervous system. Significantly, Dr. Moseley does not provide a single example of a data set showing a peripheral nerve.

[3] The only outlier is the last column of the first row of Table 1. As I explain above, though, the minimum to minimum comparison algorithm is inappropriate and can result in inconsistent results. One of skill in the art would not use this method to calculate the contrast or conspicuity. This data is irrelevant.

[4] The image in Exhibit A, figures 2 through 4 was generated using the following configuration: Philips Achieva 1.5 Tesla MRI Scanner, UCSF STIR Neurogram protocol, SENSE. The measurements were taken with an industry accepted DICOM program called Osirix from the original DICOM data set.

over 10,000 images made using the patented method, 100% of the studies that I have seen clearly met and exceed the a nerve conspicuity of 1.1 times non-neural tissues in at least one image pane in the image examination regardless of the evaluation method used. In other words, whether one calculates conspicuity using the average signal intensity (as disclosed in the patent and the literature of the time) or maximum or minimum, at least one pane in a study will have a nerve conspicuity 1.1 times non-neural tissues. The nerve is typically homogenous and bright in image panes made using the patented method. However, in some image panes, the differing internal components of the nerve will cause it to have a greater conspicuity than surrounding more homogenous tissues when the Max-Min formula is used. The claim does not require that every image pane meet the limitation, only that the data set does. Based on my experience, one of skill in the art would have no doubt determining that when the method is being practiced.

B. Dr. Moseley's Opinions Regarding Visual Conspicuity Are Both Irrelevant and Erroneous.

49. As explained above, one of skill in the art would understand conspicuity to mean what it is expressly defined as in the specification: "the contrast (in, for example, intensity or color)." This is not visual conspicuity from viewing an image, but rather an objective, quantifiable measure based on the data set. I do not view any statements from file history regarding conspicuity being "visually present" referenced in paragraph 10 of Dr. Moseley's report as altering the express definition as an objective, quantifiable measure of conspicuity disclosed by the patent and known to one having ordinary skill in the art at the time of the application. I therefore disagree that Dr. Moseley's discussion regarding visual conspicuity is even

relevant. Nevertheless, for completeness, I disagree with his conclusions (although irrelevant) regarding the objectivity of visual conspicuity.

50. I disagree with Dr. Moseley's opinion regarding reliably and objectively quantifying the conspicuity of an image visually. A person having ordinary skill in the art, for example, could use a LUT (lookup table) designed to use colors to show the differences in intensity and, therefore, conspicuity. For example, in Exhibit A, Figure 1b attached to this report, a LUT called "NIH" is used to show different colors where typical image intensity of nerve is set to a point just above a sharp color transition in the LUT. A change in intensity of 10% is a conspicuity of 1.1 times and a LUT can be used to detect and highlight differences of this scale as a visual means of assessing a qualifying degree of relative conspicuity without laborious calculations. Color differences can similarly be used to show a change in intensity of 5 times. Thus, one having ordinary skill in the art at the time knew how to reliably and objectively quantify the conspicuity.

51. A person having ordinary skill in the art would also understand that the reference to color in the definition of conspicuity used in the specification is a reference to the use of LUTs, among other things. LUTs are commonly used in the art to simplify the appreciation of contrast change. LUTs are provided along with routine diagnostic radiology interpretation DICOM viewing software such as Osirix. Similar tools are available, including ImageJ and many other viewing systems.

52. As an operational consideration, it is also important to consider that radiologists typically employ a primarily visual method of assessing medical images. As needed, they also employ quantitation such as calibrated size measurements for tumors and signal intensity measurement for determining contrast enhancement due to a contrast agent. No radiologist can use a

predominantly mathematical and quantitative approach to MRI reading because of the vast amount of data that could be involved. Images are meant to summarize complex data sets in meaningful ways, with quantitation reserved for special cases. Thus, radiologists routinely make clinical judgments based only visual assessments.

53. Further, Dr. Moseley's opinion in paragraph 14 that the visual conspicuity would vary depending on the portion of the background chosen to assess is unsupported. As I note above, regardless of the portion of the background chosen, the conspicuity will be much greater than 1.1 times in an image made using this invention. Dr. Moseley's own Table 1 in his report supports this.

54. I also disagree with Dr. Moseley's opinion in paragraphs 15 and 16. There are strict rules regulating how an image can be read for diagnostic purposes. A neuroradiologist cannot, for example, make a diagnostic reading from a paper printout as opined by Dr. Moseley. In order for a viewing system such as a DICOM printer or a DICOM viewing monitor to be qualified for diagnostic clinical use, it must be of the highest quality and part of a commitment to maximize reliable interpretation. A radiologist's duty of care would not allow him to intentionally subject a patient image to photocopying because it decreases image detail and would likely result in a substandard image interpretation would surely lose his license.

55. Furthermore, while it is certainly possible to use ImageJ and other viewing tools to measure the final printed image, and to use various viewing software programs to optimize the image for a particular radiologist's eyes, these adjustments do not alter the relative conspicuity of structures in an MRI output. This is because the DICOM data set is maintained and is the basis for measurements even if the visual representation of the data set is

presented in various different contrast configurations on a computer monitor. If tissue A has a higher intensity than tissue B, there is no legitimate manipulation of window level that renders tissue B of higher intensity than tissue A unless the entire image is uniformly inverted to a non-standard negative version. Medical imaging is fundamentally a very objective physical examination.

56. Furthermore, as illustrated in the images attached as Exhibit A, Figures 5, 6 and 7, regardless of how the contrast or window level is adjusted, the relative intensities and the result conspicuity remains essentially the same because the underlying DICOM data set that is the source of data for the signal intensity measurements does is not altered when the visual representation is changed.[5] Indeed, as one having ordinary skill in the art knew, the DICOM standard (or its predecessor NEMA standard) requires that the underlying data set remain the same regardless of the visual changes made by viewing radiologist on the monitor. As a result, in those situations where a radiologist is required to perform a calculation based on signal intensity (e.g., conspicuity), the actual data used remains consistent as the measures are made from the DICOM data set (12 bit or 16 bit) and not from the manipulated 8 bit set on the screen which radiological DICOM viewing software such as Osirix does not allow. In the NEMA and DICOM standards, once the patient image data is acquired, no user is allowed to alter the original data. Only the onscreen representation of the data may be altered.

57. Indeed, it is well known those skilled in the art that in reading an MRI image, the visual assessment of conspicuity is always subject to verification

[5] The numbers in figures 5, 6 and 7 of Exhibit A vary slightly because slightly different regions of interest are chosen.

by numerical confirmatory assessment. If a physician were to assert in a court of law that he missed a tumor because it was not sufficiently conspicuous, the plaintiff would be entitled to provide objective measurements of the brightness of the lesion and compare these to a community standard of what conspicuity constituted a reasonable duty of care for a physician in recognizing a lesion. Thus, Dr. Moseley's opinion and the images contained in Exhibit B to his report are misleading.

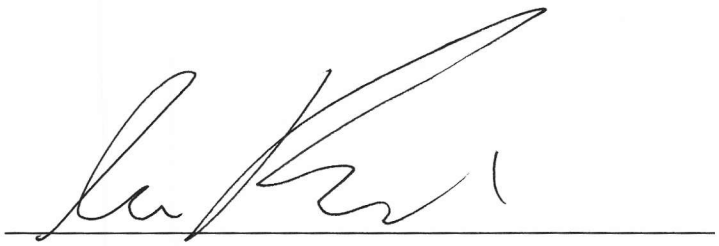
C. Dr. Moseley's Report Suffers From Other Flaws.

58. In my opinion, Dr. Moseley's report also suffers from other problems. First, in various portions of his report, Dr. Moseley uses a scan of a printout of an MRI image. A physician having ordinary skill in the art would never make a diagnostic reading using a scanned image of an MRI. In my opinion, therefore, Dr. Moseley's analysis of this scanned image is entirely inapplicable and misleading.

59. Paragraph 35 similarly expresses Dr. Moseley's opinion that conspicuity depends on how the image was handled, for example if it was scanned or compressed. A person having ordinary skill in the art, however, knows that the only diagnostically relevant (and FDA approved) MRI output is the original data or image. Dr. Moseley's opinion is therefore mistaken in this regard.

I declare under penalty of perjury that the statements in this report are true and correct.

Executed on February 1, 2011 in Santa Monica, California.



Dr. Aaron Filler, M.D., Ph.D., FRCS